



## PRIMARY CARE INNOVATION LAB (PCI-Lab)

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- ◆ Alere Inc
- ◆ Agency for Healthcare Research and Quality (AHRQ)
- ◆ Coulter Foundation
- ◆ European Union FP7 Program
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- ◆ Health Resources and Services Administration (HRSA)
- ◆ Health Care Cost Institute (HCCI)
- ◆ National Center for Advancing Translational Sciences of the National Institutes of Health through the Clinical and Translational Science Awards (CTSA) Program
- ◆ Patient Centered Outcomes Research Institute (PCORI)
- ◆ University of Washington (UW) CoMotion
- ◆ University of Washington (UW) Department of Family Medicine
- ◆ University of Washington (UW) Royalty Research Fund supported by Kathmandu University of Medical Sciences

### MISSION

The mission of the PCI-Lab is to accelerate the design, implementation, and productive use of technology that has the potential to improve primary care practice and patient health through cutting-edge research and synergistic partnerships.

## PCI-Lab LEADERSHIP

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- Sean Munson, PhD, Assistant Professor, Human Centered Design and Engineering, UW
- Jonathan Posner, PhD, Associate Professor, Mechanical Engineering, UW
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### KEY ADVISORS

- Rob Arnold, Entrepreneur in Residence and/or Patrick Shelby, Director, New Ventures, UW CoMotion
- Maura Little, Director of Economic Development for the Life Science Sector, Washington State Life Science and Global Health Center
- Rad Roberts, Director, Industry Relations, Office of Corporate & Foundation Relations, UW
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- Bernhard Weigl, Senior Platform Manager, Intellectual Ventures/Global Good, Bellevue
- Paul Yager PhD, Professor; and/or Cecilia Giachelli PhD, Professor and Chair, Department of Bioengineering, UW

We always welcome potential new collaborators and advisors interested in joining our group

## WHO ARE WE?



PCI-Lab is a core collaboration based within the University of Washington (UW) Department of Family Medicine, the #1-rated primary care program in the country according to *US News and World Report*. The UW itself ranks as the top publicly funded university for innovation in the US. PCI-Lab benefits from being in the Pacific Northwest, which is a hub of scientific and information technology development, and home to some of the world's leading high tech companies and entrepreneurs.

We exist in a unique and highly collaborative environment that leverages:

- Experienced researchers with proven expertise in mHealth, user-centered design, diagnostic devices, qualitative and quantitative methods, big data analysis, health systems, HIT adoption, insurance reimbursement, and health economics;
- The Institute of Translational Health Sciences' WWAMI region Practice and Research Network (WPRN), including 50 primary care clinics across five states with active engagement in clinical research;
- The UW School of Medicine, including its 12 UW Neighborhood clinics in the Seattle metro region with approx. 250,000 visits per year.

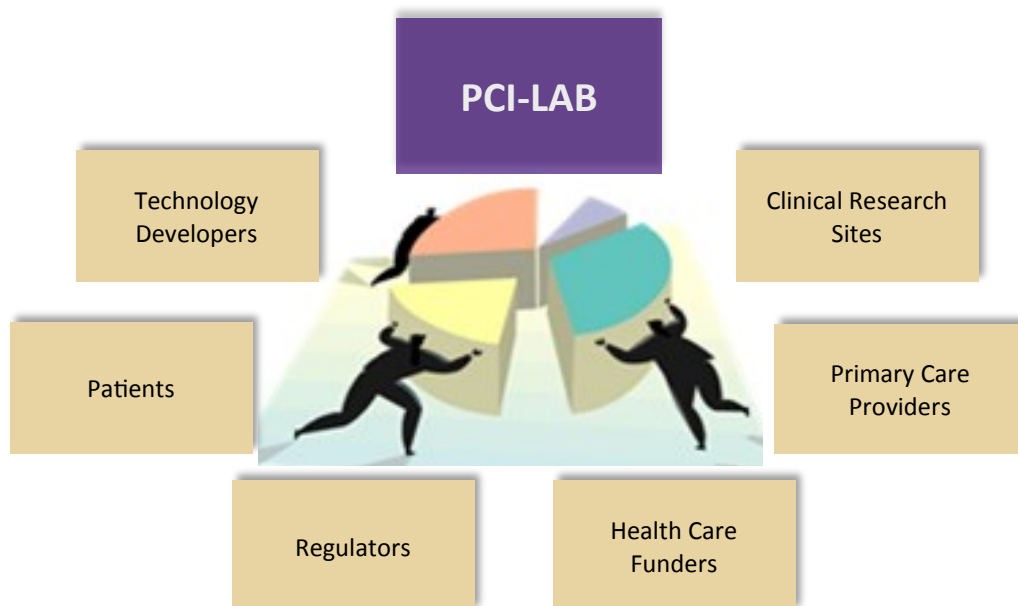


WWAMI region Practice and Research Network

## HOW CAN PCI-Lab HELP?

The primary care environment is rapidly becoming a major target for technological innovation including diagnostic tools and devices. The problem with innovation in primary care is not lack of ideas, lack of new technologies, or lack of need. A critical limitation to technological advancement in primary care is that the key stakeholders are poorly connected and often do not work together.

PCI-Lab offers expertise at all stages of the system development life cycle, from design to implementation. Any research conducted will be under the umbrella of the UW Institutional Review Board (IRB), grants and contracts management, and open publication policies. We can work under contract research, consultancy, and various public/private partnerships.



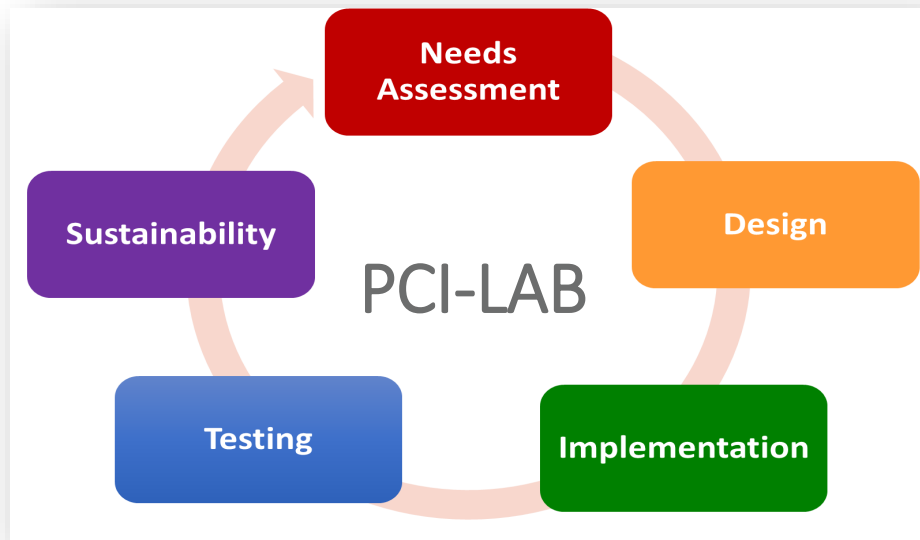
PCI-Lab

## WHAT IS OUR ECOSYSTEM?

The PCI-Lab creates an ecosystem that brings together stakeholders to design and optimize use of technological innovations in the context of primary care. Stakeholders include industry and technology developers, health care funders, device regulators, primary health care providers and their patients, and academic researchers seasoned in primary care domains. PCI-Lab engages with small and large companies, academic groups and other organizations, and from early to mature stages involved in technologies of relevance to primary care settings. PCI-Lab draws on the strengths of leading academics and world class clinicians, and leverages its connections with a “natural laboratory” of 5 million people living in geographically, culturally and economically diverse areas covering over a quarter of the US. Whenever possible, the PCI-Lab extends its reach to the diverse networks of primary care clinics across five states, including their providers, staff and patients

## WHAT EXPERTISE DOES THE PCI-Lab OFFER?

Factors of successful innovation in primary care contexts include clinical skills, needs alignment, information access, software development, creativity, integrated workflow, and management skills. The interdisciplinary collection of faculty associated with the PCI-Lab bring together the knowledge, skills and ability to work collaboratively with health organizations and industry partners (through grants and contracts) at multiple stages of the innovation cycle. The projects we pursue include needs assessment and workflow analysis, system design, implementation process and adoption, in context and usability testing, as well as scaling pilots and projects up to sustainable systems.



These projects benefit from the collective expertise of faculty associated with PCI-Lab, who are seasoned in the primary care context. Areas of expertise include

- Family medicine
- Behavioral health
- Engineering
- Human centered design
- Information Systems and information governance
- Economic
- Software development
- Implementation science

## WHY FOCUS ON PRIMARY CARE?

Primary care is a critical focal point of the health care delivery system. In the US alone there are nearly 1 billion visits to ambulatory care settings per year, of which nearly half take place in primary care clinics.

Current challenges are:

- Increasing number of responsibilities around the delivery of preventive care, coordination of care, and management of disease across a complex health system.
- Greater patient volumes as the population lives longer and ages with multiple chronic conditions, requiring lifelong monitoring.
- Delivering consistently high quality patient care across the population in a timely and efficient manner.

These challenges exist worldwide, and increasingly so in low and middle income countries where the need for effective primary care is profound, and the epidemiologic shift from acute infections to chronic disease now mirrors the major health problems of the US.

## WHAT IS WRONG WITH CURRENT TECHNOLOGICAL INNOVATION?

Providing health care that achieves the “Triple Aim” of improving the experience of care, improving the health of populations, and reducing per capita costs offers opportunities to look for new technologies that can advance solutions.

There is an expectation that new technology will:

- Revolutionize the health care system by making hospitals, clinics, and doctors’ offices more efficient and effective.
- Save billions of dollars.
- Improve patient safety and health.
- Increase the availability of care in rural underserved areas.

*Unfortunately, expectation is far from reality. Relatively little new technology gets implemented in primary care settings; much less is optimized. Health care innovations to date have largely focused on blockbuster drugs, sophisticated medical equipment, and individual health monitoring tools, not on how to improve primary care delivery.*



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*PCI-Lab aims to bring industrial, clinical, and academic stakeholders together to accelerate the research and development of emerging technologies to improve health care delivery, and/or to reduce health care costs and disease burden.*

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## CURRENT PORTFOLIO OF ACTIVITIES/EXPERTISE

	NEEDS ASSESSMENT	DESIGN	IMPLEMENTATION	TESTING	SUSTAINABILITY
PROJECT 1: Identifying Barriers to Implementing Point of Care Testing in Family Practice Clinics			✓		
PROJECT 2: Acceptability, Feasibility, Barriers and Challenges to Use of Point of Care C-Reactive Protein (CRP) Tests in Primary Care			✓		
PROJECT 3: Establishing the Priority Clinical Areas for Use of Handheld Ultrasound in Family Medicine	✓				
PROJECT 4: Impact of Electronic Health Record Adoption on Staffing and Productivity in Community Health Centers			✓	✓	
PROJECT 5: Emerging Skills for Health IT Adoption	✓				
PROJECT 6: mHealth: Measuring Primary Care Patients' Use of Mobile Health Technology	✓				
PROJECT 7: LifeLog: Sharing Patient Lifelog Data with the Primary Care Team		✓	✓		
PROJECT 8: Patient Preferences for Weight Loss in Primary Care	✓				
PROJECT 9: Patient-Centered Research for Standards of Outcomes in Diagnostic Tests (PROD)			✓	✓	✓
PROJECT 10: Next-Gen Point of Care Immunoassay	✓	✓			
PROJECT 11: User Driven Design for Technology to Assist Adolescent Overweight and Obesity Self-Management	✓	✓			
PROJECT 12: Evaluating Tempu-Ring Wireless Temperature Sensor for Ovulation Detection				✓	
PROJECT 13: Technology to Improve Perinatal Services (TIPS)	✓	✓			
PROJECT 14 Supporting Life – Mobile Decision Support to Reduce Child Mortality in Malawi		✓	✓	✓	
PROJECT 15 Integrating Mobile E-Health into Hypertension and Diabetes Management in Cambodia			✓	✓	✓
PROJECT 16: The Dhulikhel Heart Study: Evaluating and Addressing Cardiovascular Disease and Risk Factors in Nepal		✓	✓	✓	✓

## PROJECT 1    Identifying Barriers to Implementing Point of Care Testing in Family Practice Clinics



### IMPACT

Identified the facilitators and barriers to point of care tests in the substantial family medicine market.

Prioritized “most wanted” tests from provider perspectives.

Identified new clinic partners for point of care test evaluations.

### FUNDING:

UW Institute of Translational Health Sciences (ITHS)

### DESCRIPTION

Point of care tests are diagnostic tests that are conducted during consultations in the CLIA-waived labs in primary care clinics. Several of these are widely used, such as strep tests for streptococcal sore throat, or dipstick urine tests for bladder infections. The growth in the in vitro diagnostics industry for point of care tests is growing faster than other types of laboratory testing. However, implementation of point of care tests varies widely in primary care clinics, and we know little about what is limiting implementation of this new technology.

Questions include:

- Why are some tests are used and others are not?
- What barriers do clinics face with implementing point of care tests?
- What would help facilitate more tests being used?
- What information can we feed back from the “frontline” of clinics, to the developers and makers of point of care tests?

These fundamental questions have never been answered in the US, despite the potential size of the market. In this project, we aim to identify the barriers and facilitators to the use of point of care tests in family medicine clinics in the WWAMI region, using interviews and focus groups with practitioners, clinic lab staff and clinic leaders.

### WHAT THIS MEANS FOR PRIMARY CARE TECHNOLOGY

This is the first study that has explored the barriers and facilitators to using point of care tests in the substantial primary care market. Initial findings suggest significant potential benefits that clinics themselves see, such as improved clinic efficiency, enhanced clinical decision making, improved patient satisfaction. Providers also identified several “high priority” tests they would like to see added to their current tests. We also identified several potential barriers that need to be addressed in order to improve test use, such as concerns about perceived inferior accuracy, limited staffing to run tests, complexity of reimbursement, and integration with electronic health records.

## PROJECT 2      Acceptability, Feasibility, Barriers and Challenges to Use of Point of Care C-Reactive Protein (CRP) Tests in US Primary Care



### IMPACT

Determine what barriers need to be overcome in introducing point of care CRP based on the Afinion™ platform to the US health care market.

Specifically identify what gaps in knowledge and training providers have with this test, and how these could be best addressed.

Gather patient willingness to have point of care CRP tests.

### DESCRIPTION

Improving the appropriate use of antibiotics is a priority for primary care practitioners in the USA, and has been the subject of numerous “antibiotic stewardship” campaigns from professional bodies as well as the CDC. One of the issues for primary care providers and their patients, is knowing if someone presenting with cough or cold symptoms has a viral or bacterial infection. This uncertainty drives a vast amount of antibiotic prescribing, which is often unnecessary. In 2014 the White House issued a National Strategy for Combating Antibiotic-Resistant Bacteria which highlighted the need for “*rapid point of need tests that can be used during a healthcare visit to distinguish between viral and bacterial infections*”. C-reactive protein (CRP) is one such test. It has been extensively evaluated in studies in Europe and Scandinavia, where it is routinely used for adults and children attending primary care clinics with respiratory tract infection. CRP is an inflammatory marker whose levels are elevated in bacterial infections to a greater extent than viral infections, and therefore provides a way of distinguishing between viral and bacterial infections.

While CRP testing seems promising, none of the point of care tests are currently FDA approved, even though the platforms that run them are widely used. For example, the Alere Afinion™ platform for running point of care tests for HbA1c is currently used in several thousand US primary care clinics. In partnership with Alere, we are exploring the potential role of point of care CRP testing, as well as barriers to widespread implementation for guiding antibiotic prescribing for patients with acute bronchitis/cough. We will find out from health care providers and patients themselves, what they think about using a CRP test, whether it is acceptable or feasible to introduce, and how they might use this test in day to day practice.

### WHAT THIS MEANS FOR PRIMARY CARE TECHNOLOGY

This will be the first study to explore the use of point of care CRP in primary care settings in the USA. It will provide essential information to help guide the design of further studies and trials of the impact of this test on clinical practice, and make sure that the information about the test can be clearly communicated to providers and patients. Respiratory infections are such a common part of primary care, that this test could potentially have very wide uptake.

### FUNDING:

ALERE Inc.

## PROJECT 3    Establishing the Priority Clinical Areas for Use of Handheld Ultrasound in Family Medicine



### IMPACT

Prioritize areas of ultrasound that are going to be most amenable to training and skill development for hand held ultrasound scanning.

Use to direct training and reimbursement models around handheld ultrasound.

Use to direct clinical impact and cost effectiveness studies for high priority conditions.

### DESCRIPTION

Ultrasound devices have become miniaturized over the last 10-15 years, and several are now available as highly portable hand held devices. To date, most experience with handheld ultrasound has been in various hospital clinical specialties, such as assessment of cardiac structures, emergency care/trauma, orthopedics/rheumatology (to guide joint injection). There has been very little assessment of the potential roles for handheld ultrasound in primary care settings, as a result current adoption is very low.

Increasing access to ultrasound through portable devices has many potential applications in the primary care field. Some of the potential uses could be musculoskeletal (diagnosis of tendon injuries, guiding joint injections), gynecology (e.g. endometrial thickness, ovarian lesions), obstetric (e.g. first trimester bleeding, early dating, ectopic pregnancy, fetal position at term), and screening for abdominal aortic aneurysms. It is unlikely that primary care providers will be able to (or want to) become proficient in all possible areas of ultrasound. So, establishing and prioritizing the clinical user needs in primary care is essential in order to guide all further steps in the evaluation and impact of handheld ultrasound. We want to find out how often and for what reason Family Practitioners order ultrasound scans. We are using data from both WWAMI region clinics and UW Medicine clinics to determine frequency of scans and their associated diagnoses in Family Medicine clinics.

### FUNDING:

UW Department of Family Medicine

### WHAT THIS MEANS FOR PRIMARY CARE TECHNOLOGY

Determining the “best fit” for this exciting new technology in primary care is essential. The technology in this area is advancing rapidly, yet is not matched up uptake in clinic settings. Knowing what the best clinical scenarios and targets to go (and what can be reimbursed) after are critical first steps. This will guide all further steps in implementing handheld ultrasound, including testing accuracy of scanning by family practitioners, impact on clinical decision making, and training needs.

## PROJECT 4    Impact of Electronic Health Record Adoption on Staffing and Productivity in Community Health Centers



### IMPACT

Provides evidence that may inform workforce planning and workflow analysis when implementing a health technology.

The approach serves as a model for future analysis of staffing impacts of technologies within primary care settings.

### FUNDING:

Health Resources and Services Administration (HRSA) via The George Washington University Health Workforce Research Center

### DESCRIPTION

Historically, primary care settings have been slow at adopting electronic health records (EHRs). Among the major barriers to EHR adoption has been the lack of capital, lack of staff training and challenges with integrating EHRs into clinical workflow. The Health Information Technology for Economic and Clinical Health Act (HITECH) of 2009 (part of the American Recovery and Reinvestment Act) set into motion financial incentives and resources to accelerate the adoption of EHRs in primary care settings. Despite the adoption of EHRs, little evaluation or assessment has been done about the impact of EHRs on staffing in primary care settings, which this project addresses.

Using administrative data, we found that the adoption of EHRs resulted in an increase in staffing of lower skilled workers such as medical assistants for the immediate year or two after adoption. Nurse productivity was negatively affected when clinics had fewer years of experience with EHRs, which may be a result of the increase in time required to manage the EHR system. Physician productivity increased with more years of EHR experience, which may be a result of increased efficiency but also may be a reflection of task shifting.

### WHAT THIS MEANS FOR PRIMARY CARE TECHNOLOGY

Many providers, payers, and policymakers question the promise of EHRs in improving primary care delivery and efficiency. This project improves our knowledge about the complex dynamics of productivity improvement. Productivity may not be apparent at an aggregate level, but rather differentially impacts different providers.

## PROJECT 5    Emerging Skills for Health IT Adoption



### IMPACT

Identifies the technological skills in most demand.

Identifies gaps in technological skills among health care providers.

Identifies regions of the country that may face more or less challenges in finding a qualified workforce that will enable a clinic to adopt a technology.

### FUNDING:

Health Resources and Services Administration (HRSA)

### DESCRIPTION

As technologies emerge and evolve, health systems require a workforce that have the necessary skills and training to adopt and implement these technologies. While small surveys have identified the necessary and desired skills, and barriers to getting these skills, there is limited understanding about the national demand for technological skill in health care. This project uses big data—specifically data from a job search engine—to identify the most common information technology (IT) skills in demand, the types of health care providers requested to have these skills, and the rate at which employers are able to find workers with these skills.

### WHAT THIS MEANS FOR PRIMARY CARE TECHNOLOGY

Technologies are only as effective as the individual who adopts and uses them. If training is perceived as a barrier and finding providers with necessary skills is seen as a challenge, technologies face an uphill battle when seeking to be adopted and integrated into primary care clinics who already face a growing number of demands. Ideally, health care providers already have the necessary skills and training that make adoption of new technologies easy. In order to prepare a competent workforce, educational institutions need to be aware of the skill requirements demanded by employers. This project will help inform which IT skills are in most demand by health care employers and for which type of provider, and how difficult it is for health care employers to identify workers to fill these slots.

## PROJECT 6     mHealth: Measuring Primary Care Patients' Use of Mobile Health Technology



### IMPACT

Demonstrates potential “demand” for mHealth technology in primary care settings

Successful engagement of 6 diverse primary care practices across multiple states in conduct of mHealth study. These practices are likely to be interested in future mHealth research.

### DESCRIPTION

Mobile health (mHealth) has grown to be a multi-billion dollar industry in the United States. In the 2015 Pew Research Center Survey, almost two thirds of Americans own smartphones and 62% of smartphone owners report using their smartphone to get information about a health condition. mHealth tools offer patients opportunities to track and manage chronic diseases and health behaviors. Primary care is the setting in which most chronic disease care occurs. Understanding primary care patients’ use of mHealth technology is critical for guiding development and dissemination of effective mHealth tools.

In this study, we surveyed 918 patients across 6 primary care practices in the WWAMI region Practice and Research Network. Of the 55% of patients who reported owning a smartphone, 70% reported recent use of a mHealth application. Commonly cited reasons for using mHealth was finding health information (92% of mHealth users) and tracking a health condition (54% of users). Patient factors, including age and gender were associated with mHealth use. Race/ethnicity and insurance status were not associated with mHealth use, suggesting mHealth technology may be an important strategy for addressing racial and ethnic health disparities.

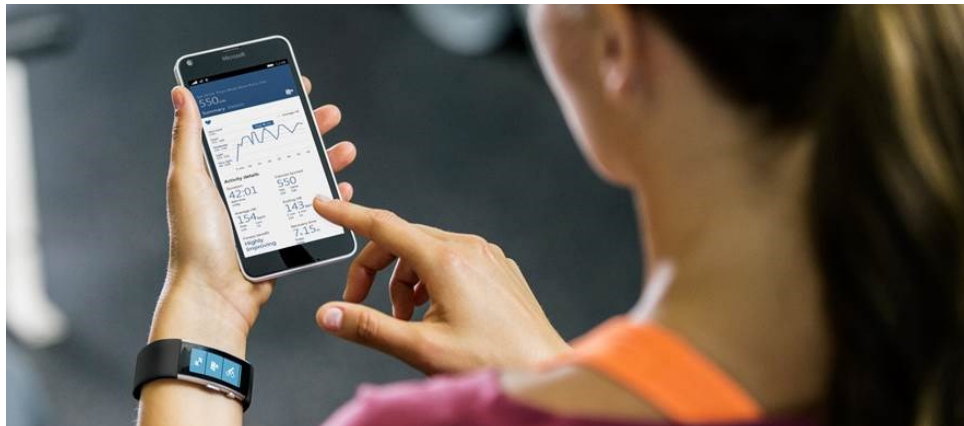
### FUNDING:

This project was supported by the National Center for Advancing Translational Sciences of the National Institutes of Health under award no. KL2TR000421 and grant UL1TR000423 through the Clinical and Translational Science Awards (CTSA) Program.

### WHAT THIS MEANS FOR PRIMARY CARE TECHNOLOGY

This study affirms the widespread use of mHealth technology by primary care patients. It suggests that development of mHealth tools to assist patients in managing chronic conditions and monitoring and tracking health behaviors may be particularly useful.

## PROJECT 7    LifeLog: Sharing Patient Lifelog Data with the Primary Care Team



### IMPACT

Identifies a critical gap in current technology for patient generated data.

Successful engagement of patients and clinicians around evaluation of use of technology in healthcare settings. Future work can build on this existing collaboration.

### DESCRIPTION

Patient generated data is increasingly common in chronic disease management. Smartphone applications and wearable technology can help patients more easily collect health information. However, the best technology approaches for supporting patients and providers in collaboration surrounding patient generated data is not well understood.

In this study, we examined patient expectations and current collaboration practices around patient-generated data. We surveyed 211 patients, conducted interviews with 18 patients and 21 clinicians. We found that patients and providers use patient generated data in different ways. Patient and clinicians perspectives suggested strategies in technology development to avoid misunderstandings and address privacy concerns.

### WHAT THIS MEANS FOR PRIMARY CARE TECHNOLOGY

#### FUNDING:

This project was supported by the Agency for Healthcare Research and Quality under award number 5R21HS023654-02.

This study demonstrates that patients and clinicians view patient-generated data in different ways and have different needs for presenting and sharing this data. Technology solutions to bridge the gaps between clinicians and providers will be critical in ensuring health benefits from patient generated data.

## PROJECT 8    Patient Preferences for Weight Loss in Primary Care



### IMPACT

Demonstrates potential “demand” for comprehensive weight loss programs in primary care

Highlights need for widely available, low cost, convenient approaches to weight loss, which may be particularly amenable to technology solutions.

### FUNDING:

This project was supported by the National Center for Advancing Translational Sciences of the National Institutes of Health under grant UL1TR000423 through the Clinical and Translational Science Awards (CTSA) Program.

### DESCRIPTION

Obesity is a significant contributor to morbidity and mortality in the United States. The U.S. Preventive Services Task Force recommends that all patients should be screened for obesity, and that obese patients be referred for comprehensive weight loss treatment. The goal of this study was to determine the degree to which overweight and obese primary care patients report willingness to participate in comprehensive weight loss programs.

In this study, we analyzed surveys from 1,632 patients across 12 primary care practices. We found that 63% of overweight and obese adults reported willingness to participate in comprehensive weight loss programs. Patients cited low cost and convenience as important factors in helping them decide about program participation.

### WHAT THIS MEANS FOR PRIMARY CARE TECHNOLOGY

This study demonstrates that primary care patients report willingness to participate in comprehensive weight loss programs. Technology solutions to delivery of evidence-based weight loss programs, including web-based, mobile health and other innovations may be important in addressing cost and logistical barriers to program participation.

## PROJECT 9      Patient-Centered Research for Standards of Outcomes in Diagnostic Tests (PROD)



### IMPACT

Identify which patient-centered outcomes are most important to include in evaluations of imaging tests.

Produce guidelines to facilitate diagnostic imaging tests' value to patients, clinicians and the health care system.

Explore how to communicate information on the comparative benefits and any potential harms of different imaging tests to consumers.

### DESCRIPTION

Imaging tests, such as X rays, ultrasound scans, CT and MRI scans are commonly used - there were approximately half a million performed last year in the USA alone. These tests have multiple roles in health care, such as detecting disease and helping to predict disease progression. However, at present, patients and their health care providers have limited ways to make informed choices about *which tests to choose*. This is because currently most evaluations of imaging tests (as well as most other kinds of tests) is based on their accuracy, which is important, but overlooks many other patient centered outcomes that may be equally important to patients. For example, a test might have reassuring effects, and give patients more knowledge about their disease and let them control a disease better. In contrast, a test might cause fear or anxiety, may cause pain or other adverse effects, or falsely reassure someone. These “patient centered outcomes” are vitally important, but currently are rarely measured or compared.

The PROD study will provide new guidelines to allow patients and healthcare provider to make more informed choices about diagnostic tests. We are exploring patient, caregiver, and health care stakeholder experiences with different types of imaging tests, and identify which patient-centered outcomes are important to them. We are using this will produce new “how to” guidelines to help “weigh up” imaging tests.

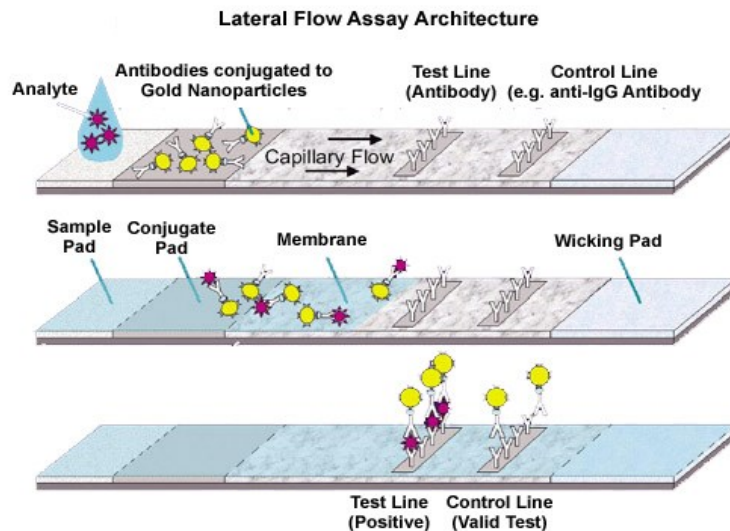
### FUNDING:

Patient Centered Outcomes Research Institute (PCORI)

### WHAT THIS MEANS FOR PRIMARY CARE TECHNOLOGY

Diagnostic imaging is one of the fastest growing areas of technology in health care. Being able to define the value of tests has always been difficult, compared to treatments or interventions. However, it is precisely this gap which the PROD research will fill. Our research involves collaboration between key players in this area, including the American College of Radiologists, diagnostic imaging industries, as well as patients and clinicians.

## PROJECT 10 Next-Gen Point of Care Immunoassay



### IMPACT

Novel, highly sensitive lateral flow tests have the potential to transform point of care testing at lower cost than new molecular based tests.

Working in collaboration with the Posner Lab at UW has been essential to guide end user needs and target product profile.

### DESCRIPTION

Lateral flow assays (LFA) have an existing market of ~\$4B and are the most prevalent rapid, point-of-care tests because they are simple to operate, provide qualitative (yes/no) unambiguous visual detection, and are inexpensive. The most common example is the home pregnancy test that shows a colored band when urine is positive for significant levels of hCG, signaling pregnancy. Many of the large number of commercially available LFA have little market penetration (e.g. Chlamydia, Gonorrhea, C. difficile, etc.) because of their lack of clinical diagnostic value; their sensitivity and specificity are just too poor compared to the gold standard (e.g. culture, ELISA, microscopy, etc.). The Posner Lab at UW has developed a new technique called Lateral flow Isotachopheresis Diagnostic (LID) technology which builds off existing LFA diagnostic technologies and appears to improve the limit-of-detection 100X.

The PCI-Lab team has been working with Professor Posner on the clinical end user needs for this type of technology, and highlighted point of care testing for group A streptococcus, as well as point of care testing for chlamydia infection as two 'most wanted' technologies. Dr Thompson is involved with the Posner Lab on development and input into preclinical testing of this emerging technology.

### FUNDING:

Coulter Foundation. Comotion

### WHAT THIS MEANS FOR PRIMARY CARE TECHNOLOGY

The global market for point of care diagnostics for infections alone is massive. While some of this will be filled with current microbiological tests, and others by emerging molecular based diagnostic tests, there is a huge market for low cost, simple to use tests, provided they are sufficiently accurate. Bridging the gap between technology developers at the earliest stage is critical to informing the target product profile of this new technology.

## PROJECT 11 User Driven Design for Technology to Assist Adolescent Overweight and Obesity Self-Management



### IMPACT

Adolescents, parents and providers want an Intensive Lifestyle Modification tool to help in daily decision making related to weight management that is convenient, fun and low cost.

Key technology requirements were identified in five areas: Food Management and Nutrition, Exercise, Social Networking, Goals and Progress, and Recipe Builder indicating that CBI could affect multiple aspects of self-management.

Results have inspired the development of integrated commercial adolescent overweight self-management systems.

### DESCRIPTION

Overweight and obesity in children and adolescents has reached an all-time high in the United States and is associated with significant clinical sequelae. Problems associated with excess weight in youths include the development of The recommendation of intensive lifestyle modification (ILM) for all overweight children is not being met in primary care. Computer-based interventions (CBI's) may be a promising way to provide behavioral support tools that can help promote healthier food and lifestyle choices and thereby improve childhood overweight in a way that is accessible and cost-effective. CBI impact relies on engagement and retention of users and appropriate integration with the continuum of care. Understanding the needs, preferences, and task flow of the patient and primary care providers is a critical foundation to create an efficacious CBI. Utilizing a User-Driven Design method to engage adolescents, parents, and providers, this project focused on the design and development of a technology-enabled solution to facilitate superior self-care for adolescent overweight and obesity and appropriate linkages to primary care providers. The project was conducted in two phases:

### WHAT THIS MEANS FOR PRIMARY CARE TECHNOLOGY

Disorders of mental health are the leading cause of disability globally and remain under-diagnosed and under-treated. Common mental disorders during pregnancy and the year postpartum (perinatal mental disorders PMD; most often depression and anxiety) affect 14-23% of women overall and as many as 50% of those with low income. They increase the risk of both poor maternal and pediatric outcomes. Low-income women and those from minority ethnic groups are simultaneously at greater risk for PMD, and less likely to receive care for these disorders. These women face a range of both patient and health services related obstacles to care. The use of patient centered eHealth strategies that accommodate end user needs holds promise to overcome a range of care obstacles for this vulnerable population. Participatory methodologies are used to improve the patient-centeredness of various interventions. Provider engagement with patients is especially valuable when designing computer-based interventions for vulnerable populations. This can help promote bilateral exchange of knowledge, help address bias and disparities in the development of new interventions, and identify and address obstacles and opportunities among patients and their providers. In this project, we utilized an iterative participatory design strategy that resulted in a suite of three eHealth tools geared to the particular support needs of low-income, ethnic/racial minority women at risk for PMD.

### FUNDING:

American Dietetics Association;  
Sustainability Center

## PROJECT 12     Evaluating Tempu-Ring Wireless Temperature Sensor for Ovulation Detection



### IMPACT

Multi-site evaluation of safety and accuracy of a continuous wireless temperature sensor for ovulation prediction.

Growing demand in primary care for wearable sensors that communicate data directly to smart phones and allow patients to take more control of their health.

### FUNDING:

Prima-Temp Inc.

### DESCRIPTION

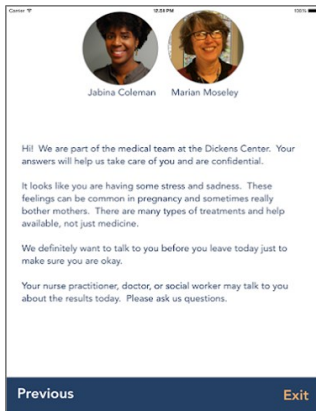
A number of diagnostic self-test kits have been developed to help women detect their time of ovulation. These methods of predicting ovulation rely on measurement of urine Luteinizing Hormone, pattern of saliva, consistency of cervical mucus, or basal body temperature. Despite a number of developments in fertility prediction, there are still a significant number of women and their partners trying to find an easy and accurate device to predict fertility.

Continuous core body temperature monitoring provides a reliable marker of ovulation prediction for conception. Prima-Temp has developed a self-inserted flexible vaginal ring (called TempuRing) that continuously monitors true core body temperature and passively communicates continuous body temperature to a smartphone app. As part of a multi-site randomized study, we are evaluating the safety and reliability of this vaginal ring sensor, by comparing the ovulation predicted by this temperature sensor with: 1) daily oral basal body temperature measures, 2) urine Luteinizing Hormone ovulation prediction kit, 3) serum progesterone levels, and 4) transvaginal ultrasound. We are also evaluating women's acceptance and ease of using this technology.

### WHAT THIS MEANS FOR PRIMARY CARE TECHNOLOGY

In this study we are focusing on a common area of concern for women who are trying to conceive, however, wireless sensing technologies like thermometry have a number of other applications in primary care.

## PROJECT 13 Technology to Improve Perinatal Services (TIPS)



### IMPACT

Using participant approaches is critical to the design of technology for use by patients and providers. This project shows that this type of methodology is usable for these efforts

The development of a decision aid for depression care in pregnancy is a critical area of work to reduce obstacles to this care.

### FUNDING:

Agency for Healthcare Research and Quality (AHRQ K18 HS02244)

### DESCRIPTION

Cultural and health service obstacles affect the quality of pregnancy care that women from vulnerable populations receive. Using a participatory design approach, the SPIRIT group developed specifications for a suite of eHealth applications to improve quality of perinatal mental health care. We established a longitudinal participatory design group consisting of low-income women with a history of antenatal depression, their prenatal providers, mental health specialists, an app developer, and researchers. The group met 20 times over 24 months. Applications were designed using rapid prototyping. Meetings were documented using field notes. The group achieved high levels of continuity and engagement. Three apps were developed by the group: an app to support high-risk women after discharge from hospital, a screening tool for depression, and a patient decision aid for supporting treatment choice. Longitudinal participatory design groups are a promising, highly feasible approach to developing technology for underserved populations.

### WHAT THIS MEANS FOR PRIMARY CARE TECHNOLOGY

Disorders of mental health are the leading cause of disability globally and remain under-diagnosed and under-treated. Common mental disorders during pregnancy and the year postpartum (perinatal mental disorders PMD; most often depression and anxiety) affect 14-23% of women overall and as many as 50% of those with low income. They increase the risk of both poor maternal and pediatric outcomes. Low-income women and those from minority ethnic groups are simultaneously at greater risk for PMD, and less likely to receive care for these disorders. These women face a range of both patient and health services related obstacles to care. The use of patient centered eHealth strategies that accommodate end user needs holds promise to overcome a range of care obstacles for this vulnerable population. Participatory methodologies are used to improve the patient-centeredness of various interventions. Provider engagement with patients is especially valuable when designing computer-based interventions for vulnerable populations. This can help promote bilateral exchange of knowledge, help address bias and disparities in the development of new interventions, and identify and address obstacles and opportunities among patients and their providers. In this project, we utilized an iterative participatory design strategy that resulted in a suite of three eHealth tools geared to the particular support needs of low-income, ethnic/racial minority women at risk for PMD.

## PROJECT 14 Supporting Life - Mobile Decision Support to Reduce Child Mortality in Malawi



### IMPACT

Estimation of potential effect of mHealth solution on child care in village clinic settings

Contribute to research methods on how to clinically validate and implement novel technologies in developing countries

Ability to test additional pediatric vital signs sensors within the android platform within this trial

Development of technology needed to improve quality of care, strengthen health infrastructure and improve disease surveillance.

### FUNDING:

European Union FP7 funding

### DESCRIPTION

In Malawi, the under-five mortality rate is 133 per 1,000 live births. To tackle premature mortality and morbidity from preventable illnesses such as Malaria and Pneumonia, the WHO and UNICEF developed Community Case Management (CCM) for use by community health workers at first-level health facilities. CCM is a paper-based clinical decision aid that uses selected clinical features to facilitate identification of children requiring urgent referral, and provide treatment for those with self-limiting illness. Adherence to the algorithm can lead to better health outcomes for children, but research consistently demonstrates both poor compliance to the tool and inaccurate measurement of vital signs, in particular breathing rate; currently limiting the effectiveness of this strategy. Preliminary evidence suggests use of smartphone technology to implement an electronic version of CCM and use of vital sign sensor technology may enhance quality of child healthcare in this setting.

The Supporting LIFE consortium is funded by the European Union, and brings together experts from the US, UK, Ireland, Sweden and Malawi in the fields of medical-based information systems, clinical research in diagnostic testing, pediatric infectious diseases and disease surveillance. It aims to evaluate the comparative effectiveness of using smartphone technology to deliver CCM in a large clinical trial. The overarching goal of this study is to improve standards of care and to establish ways of enhancing the efficiency of healthcare delivery using novel mHealth solutions.

### WHAT THIS MEANS FOR PRIMARY CARE TECHNOLOGY

Whilst electronic versions of CCM have been implemented by other organizations, none have determined the impact of mHealth solutions compared to usual care. In addition to conducting feasibility testing in rural village clinics, we will conduct the first clinical trial to generate much needed evidence to make informed decisions about the future role of smartphone and vital sign sensor technology in primary care in Malawi.

## PROJECT 15 Integrating Mobile E-Health into Hypertension and Diabetes Management in Cambodia



### IMPACT

Demonstrates use of electronic data in a low-income setting to improve communications between patients and providers.

Documents use of phone-based mhealth tools to improve cardiovascular disease outcomes.

### DESCRIPTION

Life expectancy has increased dramatically over the last few decades in many low-income countries driving the rate of previously unknown non-communicable diseases (NCDs) skyward. Ischemic heart disease and stroke are now the top two causes of mortality in Cambodia and rates of cardiovascular risk factors including hypertension and diabetes are dramatically increasing. In 2004, a non-governmental organization (NGO) based in Phnom Penh, MoPoTsyo Patient Information Center, initiated a peer educator model to address this problem. MoPoTsyo is currently delivering self-management training and medications to over 21,000 hypertensive and diabetic patients in Cambodia. In spite of the considerable success this model has demonstrated, control of these conditions – particularly hypertension among non-diabetics – remains a challenge.

The primary aim of this application is to enhance the communication network between the MoPoTsyo patient database, Peer Educators, pharmacies, and patients, using mobile eHealth tools to activate better compliance with treatment guidelines. In addition to providing wireless links to allow electronic data transfer between relevant users of the system, we are testing a mobile phone application which includes voice messaging in Khmer for interactive tailored reminders to patients for improving support for treatment adherence and goal achievement.

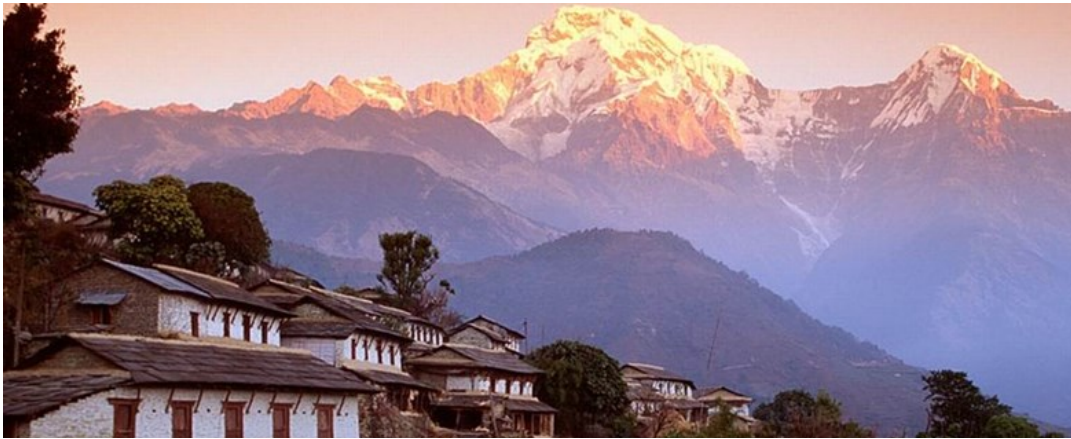
### FUNDING:

This project is supported by the Fogarty International Center of the US National Institutes of Health (1R21TW010160-01).

### WHAT THIS MEANS FOR PRIMARY CARE TECHNOLOGY

This study, planned for completion in 2018, will document the use of electronic data transfer from homes to clinics and pharmacies while also improving self-management of CVD via culturally tested mhealth applications.

## PROJECT 16 The Dhulikhel Heart Study: Evaluating and Addressing Cardiovascular Disease and Risk Factors in Nepal



### IMPACT

One of the first longitudinal cohorts in Asia to provide ongoing surveillance for understanding risk factors and sequelae of socio-demographics, lifestyles and interventions for CVD.

Provides a platform for development and testing of new devices and procedures for use in low-resource settings.

### DESCRIPTION

The Dhulikhel Heart Study (DHS) is a longitudinal cohort study of Cardiovascular Disease (CVD) and its risk factors of adults age 18 years and older living in the town of Dhulikhel, about 35 km northeast of Kathmandu, Nepal. This ongoing study is the result of over 8 years of collaborative design and testing with our colleagues at Dhulikhel Hospital – Kathmandu University School of Health Sciences with a commitment to 20 years of follow-up. The DHS has become an intervention itself as participants screened and found to have hypertension, diabetes or other non-communicable disease are brought to Dhulikhel Hospital for counseling and/or treatment. This study has provided a foundation for implementation and testing of new procedures and devices for improving the health of the population. We have begun to utilize EKG and echocardiography to provide more sophisticated diagnosis and to launch new interventions for treating CVD. Efforts are now underway to expand the tools and methodologies utilized in this suburban setting to reach residents in rural communities outside of Dhulikhel.

### FUNDING:

This project was funded by the UW Royalty Research Fund and is currently supported by Kathmandu University of Medical Sciences.

### WHAT THIS MEANS FOR PRIMARY CARE TECHNOLOGY

In addition to developing and implementing tools and methods for primary care delivery, this study can serve as a well-characterized cohort for testing new devices and procedures. Of special interest are e-tools and mhealth applications to improve point-of-care delivery of needed screening and treatment options.

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